

Attorney Docket No.46393-0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ellen R. BOLTE  
Serial No. : 09/866,033  
Filing Date : May 25, 2001  
Title : METHOD FOR TREATING A MENTAL DISORDER  
Examiner : Chih-Min Kam  
Group/Art Unit : 1653

Commissioner for Patents  
Washington, D.C. 20231

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
OR IN A NAFTA OR WTO MEMBER COUNTRY  
TO OVERCOME A CITED PATENT OR PUBLICATION  
37 C.F.R. § 1.131

PURPOSE OF DECLARATION

1. This declaration is to establish completion of the invention in this application in the United States, at a date prior to January 2000, that is the effective date of the Sandler et al., CID 30, 213-214 (January 2000) prior art publication that was cited by the Examiner.

2. The person making this declaration is the inventor.

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### FACTS AND DOCUMENTARY EVIDENCE

3. To establish a date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

\_\_\_\_\_ sketches

\_\_\_\_\_ blueprints

\_\_\_\_\_ photographs

\_\_\_\_\_ reproduction(s) of notebook entries

\_\_\_\_\_ model

☒ supporting statement(s) by witness(es) (where verbal disclosures are the evidence relied upon)

### DILIGENCE

4. Attached is a statement establishing the diligence of the Applicant, from the time of her conception to a time just prior to the filing of this application.

### TIME OF PRESENTATION OF THE DECLARATION

5. This declaration is submitted prior to final rejection

### DECLARATION

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the united States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### SIGNATURES

7. Inventor

Full name of sole inventor: Ellen R. Bolte

Country of Citizenship: United States of America

Residence: 705 Misty Creek Drive

City and State/Province: New Lenox, Illinois

Country and Zip/Postal Code: 60451

Mailing Address: (Same as above)

Inventor's Signature: Ellen R. Bolte

Date: June 30, 2003

**SUPPORTING STATEMENT BY ELLEN R. BOLTE**

I, Ellen R. Bolte, am an author of the Sandler et al., CID 30, 213-214 (January 2000) prior art publication entitled, "Relief of Psychiatric Symptoms in a Patient with Crohn's Disease After Metronidazole Therapy" cited by the Examiner. I first conceived of the idea for the invention in this application in 1995. I approached Dr. Richard Sandler in 1996 to assist me in testing my invention. Prior to the January, 2000 effective date of the Sandler et al. reference, I invented the invention in this application. Through case study and data analysis that began prior to and was the subject matter of my publication entitled, "Relief of Psychiatric Symptoms in a Patient with Crohn's Disease After Metronidazole Therapy"; *Clin. Infect. Dis.*; 2000; 30:213-214, I created the invention in this application.

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data

Full name of sole inventor: Ellen R. Bolte  
Country of Citizenship: United States of America  
Residence: 705 Misty Creek Drive  
City and State/Province: New Lenox, Illinois  
Country and Zip/Postal Code: 60451  
Mailing Address: (Same as above)

Inventor's Signature: Ellen R. Bolte

Date: Jan. 30, 2003

**STATEMENT ESTABLISHING THE DILIGENCE OF THE APPLICANT**

I, Ellen R. Bolte, from the time of my conception of the invention in this application to a time just prior to the filing of this application was diligent in my attempts to secure patent rights in my invention. My diligence is demonstrated by my filing of three (3) provisional patent applications prior to the present application and claiming the benefit of priority from said applications. The three (3) provisional patent applications that I filed and claimed benefit of under 35 U.S.C. § 119(e) in the present application are: 60/209,712, filed on June 5, 2000; 60/214,813, filed on June 28, 2000; and 60/240,582, filed on October 16, 2000.

My diligence is further demonstrated by my continued research in the subject matter of my invention of the present application from prior to the publication date of the cited reference to the filing date of the present application. Such research contributed to the invention of the present invention.

Full name of sole inventor: Ellen R. Bolte

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Inventor's Signature: Ellen R. Bolte

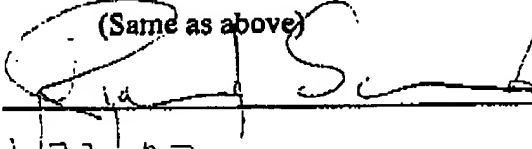
Date: Jan. 30, 2003

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## WITNESS STATEMENT

I, Richard H. Sandler, M.D., was originally approached by Ellen R. Bolte in June, 1996, with her idea that certain mental illnesses could be treated by antimicrobial therapies. I assisted Ellen Bolte in testing her idea, but hereby declare that the original idea and the invention in her patent application, Serial No. 09/866,033, are solely hers. I am the lead author of the Sandler et al., CID 30, 213-214 (January 2000) prior art publication entitled, "Relief of Psychiatric Symptoms in a Patient with Crohn's Disease After Metronidazole Therapy" and Ellen Bolte is a co-author of the article. As indicated above, Ellen Bolte invented the invention prior to the January, 2000, publication of this article. } by others

## SIGNATURE

Full name of witness: Richard H. Sandler, M.D.  
Country of Citizenship: United States of America  
Business address: Rush Children's Hospital  
1725 W. Harrison Ave., Suite 946  
City and State/Province: Chicago, Illinois  
Country and Zip/Postal Code: 60612  
Mailing Address: (Same as above)  
Witness's Signature:   
Date: 1/22/03